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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: )  
MESSADEK, Jallal )  
5 Application Ser. No. 09/945,391 ) Group Art Unit: 1614  
Filed: August 31, 2001 )  
Glycine betaine and its use ) Examiner: Clinton T. Ostrup

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DEC 05 2003  
TECH CENTER 1600/2900

**DECLARATION OF JALLAL MESSADEK PURSUANT TO ART 37 C.F.R. 1.132**

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1. I, Jallal Messadek, a citizen of Belgium and residing in Liege, Belgium, make the following declaration in support of the above-referenced patent application filed and now pending in the United States Patent and Trademark Office. I am over the age of eighteen, under no disability, and fluent in English and understand the following  
15 statements made in support of this application.

2. I carefully read the Office action and have the following comments to make.

3. The claims have been amended so as to take into account examiner's remarks.

4. For example, claim 1 has been amended so as to specify:

- that the method is directed for treating human at risk to suffer from thrombosis of  
20 arterial or venous origin ;
- that the patient is a human ;
- that the effective amount of glycine betaine is administered daily ; and
- that the administration is carried out by oral dosage form, subcutaneous injectable dosage form and patches.

25 5. Claim 4 has been amended so as to specify that the method is directed for treating human at risk to suffer from thrombo-embolic diseases of arterial or venous origin not induced by hyperhomocysteinuria or homocystinuria, that the effective amount of glycine betaine is administered daily, that glycine betaine is used as antithrombotic agent, and that the administration is carried out by oral dosage form, subcutaneous injectable dosage form  
30 and patches. Paragraphs 0002, 0016, 0190 and 0137 of the description give the support for this amended claim. Thrombo-embolic disease is a technical term obvious for the skilled man. For this, please compare passage from my description, paragraph 0016:" Thrombo-



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2. In support of the response to the Office Action in the underlying International Application PCT/BE00/00021, tests have been performed under my supervision showing the difference existing between glycine betaine and gamma butyrobetaine. These tests are disclosed and more fully set forth in the following paragraphs and attachments which are fully incorporated by reference herein.

3. For these tests, the following material was used:

Gamma butyrobetaine from SIGMA-ALDRICH®;

Anhydrous betaine BETAFIN® (Finnsugar Bioproducts, Cultor, Helsinki, Finland);

Rats (Wistar), males, weight between 250 and 300 grams, n=5/lot and per test;